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Thirty Years Later: The Outlook for Hatch-Waxman 2014
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I am pleased to join you today, even if only by video. Needless to say, the focus of this conference, the Hatch Waxman Act, is near and dear to my heart.

History

Thirty years ago, the U.S. generic drug industry was in severe decline. The 1962 amendments to the U.S. drug law required that manufacturers demonstrate that their drugs were not only safe, but also were effective. This was a reaction to the thalidomide tragedy in Europe, and was a great advance in drug oversight in the United States. However, it was a real problem for generic drug manufacturers. FDA interpreted this effectiveness requirement to mean that generic drug manufacturers had to conduct full clinical trials on drugs that had already been shown by the brand manufacturer to be safe and effective. These trials were not only unnecessary, they were effectively a death knell for generic manufacturers.

Yet many in Congress were focused only on helping the brand industry, which was clamoring to receive patent term restoration for the time expended in meeting the 1962 requirements.

In the end, we passed balanced legislation, which supported both innovation and competition. The legislation has proved to be wildly successful. Over eighty per cent of all U.S. prescriptions are now filled by generics. And for drugs for which there is a generic available, generics comprise over 90% of the drugs sold. The U.S. healthcare system and consumers saved over $200 billion dollars last

year due to generic drugs, and well over a trillion dollars over the last decade. At the same time, the brand drug industry continues to be one of the most profitable sectors in the United States.

Abuses and Controversies

Of course, Hatch Waxman was and is not perfect, and we have had to fix things as companies found ways to delay generic drug competition. One current problem is the use by brand manufacturers of Risk Evaluation and Mitigation Strategies, or REMS, to prevent or delay generic competition. Sometimes, the REMS are used as an excuse for refusing to sell the brand drug to generic drug companies. Without the drug, the generic manufacturer cannot conduct the bioequivalence studies necessary for approval. Sometimes a brand manufacturer will find ways, through patents or other means, to make it difficult for a generic manufacturer to implement a REMS procedure that FDA mandates as a condition of approval.

Another way that companies have exploited loopholes in Hatch Waxman is through the use of so-called reverse-payment settlement agreements. These are agreements in which a patent holder pays a potential competitor not to challenge its patent. Last year, the Supreme Court found that courts should look at factors such as the size of the payment to help decide whether a settlement was anticompetitive. The Supreme Court's opinion made it clear that while settlement agreements with reverse payments are not necessarily illegal, they should be viewed with suspicion.

I want to be clear that I am not against patent settlements *per se*. I recognize that it can be in everyone's interest to avoid costly and time-consuming patent litigation. However, when a generic firm commits to stay off the market in exchange for payment, there is huge potential for abuse. The President, in his 2015 budget, recommends passage of legislation that would give the Federal Trade Commission greater ability to block anticompetitive patent settlements that involve payments. I think the Supreme Court decision was helpful, but I also think that legislation such as proposed by the President would improve things even more.

In addition to trying to fix existing problems with Hatch Waxman, we have to be on the alert for legislation that might create new problems. One such bill is the MODDERN Cures Act. It has forty co-sponsors, almost half of whom are Democrats. Its ostensible purpose is to provide incentives for development of promising drugs that have been abandoned because of lack of patent protection. Proponents of the bill refer to such drugs as dormant therapies. There may well be a need to figure out how to increase the incentives to develop such drugs. I am always interested in finding better ways to incentivize the development of needed new medicines. I think my work to get the Orphan Drug Act passed demonstrates that beyond dispute.

However, MODDERN Cures goes way beyond incentivizing development of dormant therapies. Instead of the careful balancing of innovation and competition that we achieved in Hatch Waxman, this bill as currently written would give 15 years of market exclusivity, post approval, to almost any drug that was considered to fulfil an unmet medical need. That is even worse than the 12 years of exclusivity the ACA gave biologics.

We give only seven years market exclusivity to orphan drugs, and those are for diseases that affect fewer than 200,000 Americans. And the Orphan Drug Act has been, by all accounts, a resounding success in bringing new drugs to market. I suspect that many of the supporters of MODDERN Cures do not understand its potential, at least in its current form, to undermine the generic drug approval process and the generic drug industry.

The last issue I would like to address regarding Hatch Waxman and the generic drug industry is the effect created by the 2011 Supreme Court decision, Pliva v. Mensing. In that decision, the Supreme Court ruled that, because generic drug manufacturers need to first seek FDA approval before putting a new safety warning on their products, they could not be sued for failing to comply with state warning label requirements. I had submitted an amicus brief supporting the Administration's alternative view, which was that generic drug manufacturers should be held liable if they did not seek FDA approval for a new warning label when warranted. The Supreme Court did not agree.

The Supreme Court decision led FDA to review its regulations regarding manufacturers' ability to update promptly certain components of their safety labeling to reflect data obtained through postmarketing surveillance. Last year it published a proposed rule that would treat brand and generic manufacturers the same with regard to such label changes. It would allow generics, like brands, to update safety labeling prior to receiving FDA approval. It establishes a mechanism to provide information about the change to other manufacturers and to practitioners and patients. And it establishes procedures to minimize the time during which there would be temporary labeling differences among products.

FDA believes this process will help get new drug safety information out to patients and doctors more quickly. They argue it also will restore state tort liability, which serves as an important incentive for generic drug manufacturers to comply with post-approval monitoring and reporting requirements. FDA has long believed that the state tort liability system is a critical complement to FDA's compliance and enforcement activities.

One trade-off is that there may be more temporary differences in labeling among products than occurs now, when only the brand can change its label on its own. However, currently there are also temporary labeling differences between brands and generics, so the FDA rule would not be drastically changing the situation.

Another trade-off is that more liability can mean higher cost of liability protection. The generic drug industry operates on thin margins, so any added costs are noticeable. However, I think the purported new costs to the industry have been grossly exaggerated. The economic analysis put out by the Generic Pharmaceutical Association took a very broad brush approach and did not look at any actual insurance costs borne by the industry. Perhaps most critically, it provided no data on how much the industry spent on liability insurance prior to the Mensing decision.

Prior to Mensing, companies had to defend themselves against state failure-to-warn cases. By effectively setting the cost of that liability insurance at zero, the study necessarily exaggerates the economic impact of the FDA rule.

The bottom line for me is that patients should have full confidence in all aspects of generic drugs, including that they have the same right of redress whether they take a brand or generic.

Sovaldi

Consumer confidence in generics and biosimilars, and consumer access to these products, will be increasingly important as the brand industry charges higher and higher prices for innovative new drugs and biologics. Perhaps the most striking example of this trend is Gilead's Hepatitis C drug Sovaldi.

From what I understand, Sovaldi is a truly remarkable advance in treating Hepatitis C. It has a cure rate of 90%, far above that of any other treatment. The treatment takes only 12 weeks, half the time of other treatments. And it does not have the awful side effects that make the other treatments intolerable for some patients. It thus can make a real difference in the lives of the more than three million Americans with a chronic Hepatitis C infection.

However, at a cost of $1,000 a pill, many patients may not be able to get the drug. A 12 week course will run $84,000. When given in combination with the other drugs required for treatment, total costs reportedly can reach $150,000. Hepatitis C infection is concentrated in low-income minority patients, so the cost will be a particular problem for state Medicaid programs and their patients.

I do not begrudge companies making a profit, doing well by doing good. But charging such exorbitant prices for new drugs is a trend that can ultimately bankrupt our healthcare system. That is not in anyone's long term interest, even if some companies may believe it is in their short term interests.

Biosimilars

Sovaldi is a drug, not a biologic, but most of our most expensive new medicines are biologics. That is why it was so important that Congress establish a pathway for the approval of less expensive biosimilar versions of biologics as part of the Affordable Care Act. The law was by no means perfect. The ACA gave brand biologics 12 years exclusivity. I think 12 years is too much.

When we were working on the legislation, I was pushing for five years of exclusivity, which would be the same as that for conventional drugs. The President has proposed in this year's budget that the period be reduced to seven years, as he has in past budgets. I hope he will be successful in reducing the time period. FDA has been making great progress in implementing the law. It has been holding public meetings, developing guidances, and putting in place the policies necessary for review and approval of biosimilar applications. I hope that the agency will continue its good work in this area.

One biosimilars issue to watch closely as FDA implements the law is how FDA will require them to be named relative to their brand reference product. Will a biosimilar, like a generic drug, have the same International Nonproprietary Name, or I-N-N, as its reference product, or will it be required to have a different one?

FDA needs to be confident that the INN will not lead to patient confusion or medication errors, and will not impede the tracking of adverse events. The choice of INN also should not impede access to biosimilars, particularly those that are interchangeable with the reference product. The real savings from biosimilars will come with those found to be interchangeable with the reference product, so we do

not want to impose any unnecessary barriers to their use. I am optimistic that FDA is moving towards an approach that both protects patients and ensures patient access to these important medicines.

However, I am not so optimistic about another set of activities aimed at interchangeable biosimilars. BIO and a few companies, both brand and generic, are trying to get states to enact laws that will require pharmacies to notify a patient's physician before dispensing an interchangeable biosimilar. These policies are being touted by supporters as necessary to protect patients and keep physicians informed of the medicines their patients are receiving.

I fear the more likely effect will be to stigmatize interchangeable biosimilars and make patients and physicians think twice before using them. I find it somewhat ironic that BIO is pushing for these state laws at the same time as it is fighting attempts by some advocacy organizations to get states to require special labeling of biotech foods, claiming that such labeling will stigmatize those foods.

There is little dispute that biologics are part of the future of medicine. But these life-saving therapies will be worth little if no one can afford them. So we need to make sure that policies are in place that will permit biosimilars to fulfill their potential to bring competition and lower prices to this market.

Close

I want to close by thanking you for the opportunity to speak to you today, in this year of the 13th anniversary of Hatch Waxman. I am proud of the success the law has had in bringing competition to the marketplace. As many of you know, I will not be running for office after this term. I have not decided what I will be doing after I leave Congress, but you can be assured I will continue to work to

promote competition and innovation in our prescription drug industry and to increase the use of generic medicines worldwide.

Thank you. I would be happy to take any questions you may have.